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Jordan and Hamburg
122 East 42nd Street
New York, NY 10168

EXAMINER

MYERS, CARLA J

| ART UNIT | PAPER NUMBER |
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1634

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

84

Office Action Summary

Application No.

09/869,206

Applicant(s)

FRIZSCHE ET AL.

Examiner

Carla Myers

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to the amendment filed February 4, 2004. All rejections not reiterated herein are hereby withdrawn. This action contains new grounds of rejection and is made non-final.

THE FOLLOWING ARE NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-24 are indefinite over the recitations of "or via further specific binding molecules" and "said are being accessible to said complementary associated binding partners." The claims first define an area in terms of the fact that specific binding members are immobilized on the area and that these specific binding members bind complementarily associated binding partners directly or bind specific binding partners. The claims then define the area as being accessible to the complementarily associated binding partners. The claims do not define the area in terms of it being accessible to specific binding molecules. Accordingly, it is unclear as to how the recitations regarding the accessibility of the area apply to the claims. For example, it is unclear as to whether the accessibility limitation applies only to affinity sensors with an area having immobilized thereon binding partners for binding complementarily associated binding

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partners or if this limitation is intended to apply to affinity sensors with an area having immobilized thereon binding partners for either binding complementarily associated binding partners or for binding specific binding molecules. In the later case, the claims should be amended to clarify that the area is also accessible to the "further specific binding molecules."

Claims 1-24 are indefinite over the recitation of "by affinity binding with said immobilized specific binding partners to form a respective tunnel contact junction between the particle and the electrodes" because it is unclear as to what constitutes a "tunnel contact junction." The specification does not define this phrase and does not describe the interaction between the particle and electrode in terms of a "tunnel contact junction." Rather, at page 12, the specification states that when a voltage is applied across the electrodes, the electrons tunnel from particle to particle and to the electrodes. At page 16, the specification states that "(t)he nano-gaps formed by the electrically conductive particles 62 result in that an electron transfer is possible between the two contact faces of the micro-electrodes 21 by virtue of the tunnel effect." However, the specification does not teach what is intended to be encompassed by the "tunnel contact junction." Additionally, it is unclear as to how this recitation is intended to further limit the claims. The claims define the affinity sensor in terms of a functional activity – that is, in terms of an event that occurs if a binding partner provided with an electrically conductive particle bind to the immobilized specific binding partner. However, the claims are drawn to an apparatus and not to a method or to the final apparatus that contains the bound complementary associated binding partner provided with an

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electrically conductive particle. Therefore, it is unclear as to how the recitation of "to form a respective tunnel contact junction" is intended to further limit the structure of the affinity sensor.

Claims 2-24 indefinite over the recitation of "detecting specific molecular binding events as claimed in claim 1" because this phrase lacks proper antecedent basis. Claim 1 refers to an affinity sensor for detecting specific binding events, but does not refer to an affinity sensor for detecting specific **molecular** binding events.

Claim 3 is indefinite over the recitation of "cover said area with a thickness which permits tunnel effects." It is unclear as to how this recitation is intended to further limit the claim. The claim previously refers to a "tunnel contact junction" but does not previously refer to a "tunnel effect." Claim 3 does not clarify what constitutes the tunnel effect and thereby it is unclear as to what thickness would be required to permit a tunnel effect.

Claims 7-16 are indefinite over the recitation of "said predetermined area includes affinity areas at least between respective opposing ones of said electrodes" because it is unclear as to what "ones" refers to and it is unclear as to what is intended to be encompassed by this phrase.

Claim 9 is indefinite over the recitation of "the chip surface is formed by a silicon wafer" because it is unclear as to whether the chip surface consists of a silicon wafer or if a silicon wafer is to be used to create a chip surface. In the latter case, it is unclear as to how this recitation is intended to limit the structure of the affinity sensor since the

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claim is drawn to an apparatus and not to a method of making an apparatus. Similarly, claim 10 is indefinite over the recitation of "formed by a glass target."

Claim 12 is indefinite over the recitation of "a length of the micro-electrodes is 0.1 mm" because it is not clear as to whether this is in fact the length of the micro-electrode, or if this one possible length of the micro-electrode, but the claim does not require that the micro-electrode is of any particular length. Further the claim is indefinite over the recitation of "its effective height" because the claim does not clearly set forth what height is being defined. Further, it is unclear as to what is intended to be meant by "as well as the affinity areas is at a 1:10 ratio relative to the chip." It is unclear as to whether this phrase refers to the fact that the height of the affinity area is .02um or that the height of the affinity area (and the area) is at a 1:10 relative to the area of the chip surface.

Claim 13 and 16 are indefinite over the recitation of "which carries inactive binding partner" because it is not clear as to whether the inactive binding partner is also immobilized to the reference area or if the reference area only has the potential to bind or by some other means "carry" the inactive binding partner. Claim 14-16 are indefinite over the recitation "occupation densities of the specific binding partners" because the specification does not define what constitutes an "occupation density" and there is no fixed definition in the art for this phrase. Further, the phrase "the individual affinity areas" lacks proper antecedent basis. While the claim previously refers to affinity areas, the claim does not previously refer to "individual affinity areas."

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Claims 13-16 are indefinite over the recitation of "inactive binding partner" because the claims do not clearly set forth the properties of the inactive binding partner and do not clarify how the inactive binding partners are distinct from the specific binding partners. Claim 13 states that the reference area carries inactive binding partners for "a reference measurement." However, the claim is drawn to an apparatus and not to a method and does not include a step of performing a reference measurement. It is unclear as to how the recitation of "reference measurement" further defines the structure of the inactive binding partners and thereby it is unclear as to what constitutes an inactive binding partner. Further, with respect to claim 16, it is unclear as to what is intended to be meant by "different inactive binding partners." It is unclear as to whether the inactive binding partners are different from one another, different from the specific binding partners, or different from some other unspecified molecule.

Claim 16 is indefinite over the recitation of "reference areas is provided occupied with different inactive binding partners" because the claim does not clearly set forth what is intended to be encompassed by "occupied" and it is unclear as to whether the inactive binding partners are immobilized onto the reference areas or by some other unstated means are associated with the reference areas.

Claim 17 is indefinite over the recitation of "the specific binding partners enter into chemical coordination." The claim defines the binding partners in terms of a functional activity. However, the claims are drawn to an apparatus and not to a method. Therefore, it is unclear as to how this limitation is intended to further limit the structure of the affinity sensor.

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Claim 23 is indefinite over the recitation of "the nanometer range" because it is unclear as to what is encompassed by this range. For example, it is unclear as to whether particles in this range are limited in size to 1-9 nm or if the particles may be 100 nm, 1000 nm, 10,000 nm etc.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 3, 17-18, 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamashita (U.S. Patent No 5,646,420).

Yamashita (see column 1) discloses an apparatus that comprises a solid support provided with a pair of electrodes. A supporting protein material is positioned between the electrodes having immobilized thereon a quantum dot means, such that the quantum dot means is at a distance from the electrodes with a "space suitable for tunnel phenomena generation" (see column 1, lines 54-64). Yamashita (column 2, lines 5-16) teaches that the quantum dot means may be a flavin. Flavin is considered to be a "specific binding partner" because it is well known that flavin is capable of binding to specific binding regions of enzymes. Further, the area between the electrodes is considered to be accessible in some manner to a complementary associated binding partner. It is noted that the recitations regarding the electrically conductive particle and the tunnel contact junction do not further limit the claimed apparatus in terms of its

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structure and thereby do not distinguish the claimed apparatus over the apparatus taught by Yamashita. Additionally, the recitation in the claims of "Affinity sensor for detecting specific binding events" constitutes an intended use of the apparatus and also does not further limit the structure of the claimed apparatus over that of Yamashita. The claimed apparatus is anticipated by the apparatus of Yamashita since Yamashita teaches an apparatus having each of the structural properties of the presently claimed apparatus, i.e., a carrier substrate having two electrodes with a predetermined area there between, said electrodes being an equal distance from each other and bordering an area having immobilized thereon a specific binding partner.

With respect to claim 2, Yamashita (column 5 lines 32-34) states that the apparatus "can be fabricated on the order of a nanometer." Thereby, the area is considered to have a width of under 800 nm.

With respect to claim 17, it is noted that the recitation of "the specific binding partners enter into chemical coordination" does not further limit the structural properties of the apparatus. Further, flavin has the property of being capable of entering into chemical coordination.

With respect to claim 18, flavin is considered to be a bioactive molecule since it acts upon and influences bodily functions.

With respect to claims 22-24, it is again noted that the claims are not drawn to an apparatus having comprising conductive particles. The claims refer to the conductive particles only in terms of the fact that the area is accessible to complementarily associated binding partners provided with conductive particles. The claims do not

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define the area or the accessibility of the area with respect to the size or composition of the conductive particle. Accordingly, the recitations in claims 22-24 do not further distinguish the claimed apparatus over that of Yamashita.

RESPONSE TO ARGUMENTS:

In the response of February 4, 2004, Applicants traversed the previous grounds of rejection. Applicants arguments have been fully considered to the extent that they apply to the present grounds of rejection. Applicants traversed this rejection by stating that Yamashita teaches a transistor and does not teach an affinity sensor. Applicants cite Wang as showing that affinity sensors detect binding of a target analyte. However, the claims are drawn to an apparatus and not to a method of using an apparatus. The claims are examined based on the structural limitations of the apparatus and not on how the apparatus is to be used. There is no requirement for Yamashita to teach that the apparatus disclosed therein is to be used for detecting the binding of an analyte.

Applicants further traversed this rejection by stating that the apparatus of Yamashita is not capable of sensing the presence or absence of binding by the complementary binding partner. However, the structure of the presently claimed apparatus does not specifically require this limitation. The claimed apparatus is defined in terms of the fact that it comprises an area accessible to a "complementarily associated binding partner." It is unclear as to whether the area is also accessible to the "further specific binding molecules." Thereby, this limitation does not further limit the claim with respect to apparatus' that include an area having immobilized thereon a specific binding partner (such as flavin) for the binding of "further specific binding molecules." Additionally, as

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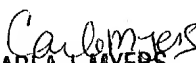
discussed in the above 112, second paragraph rejection, the recitation that the area is accessible and has a minimum width to allow for affinity binding with complementary specific binding partners to form a respective tunnel contact junction does not further limit the structure of the apparatus itself so as to require that the apparatus "senses" the presence or absence of a bound complementary binding partner.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571)-272-0782.

Papers related to this application may be faxed to Group 1634 via the PTO Fax Center using the fax number (703)-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Carla Myers
May 3, 2004


CARLA J. MYERS
PRIMARY EXAMINER